REMARKS

Claims 7, 10-12, 28-35, 37-40, 43, 46. and 54-59 are pending in the application with entry of this Amendment. Claims 7, 12, 28, 29, 43 and 54-56 are currently amended. The amendments do not present new matter, particularly considering that support for a claim amendment can be found in the claims as filed, the written description and/or the figures. *See, e.g.*, Figs. 29-32. Claim 47 is canceled without prejudice. Claims 12 and 29 were withdrawn from consideration. It is respectfully requested that these claims be reinstated upon allowance of respective independent claims from which they depend. Reconsideration and allowance of the application, as amended, are respectfully requested.

I. Withdrawn Rejections

Applicant acknowledges that the following rejections were withdrawn following the Amendment submitted on July 24, 2008:

a. Rejection of claims as allegedly being anticipated by U.S. Patent No. 4,469,105 to Staver (hereafter "Staver").

b. Rejection of claims as allegedly being unpatentable over Staver in view of U.S. Patent No. 4,736,749 to Lundback (hereafter "Lundback").

c. Rejection of claims as allegedly being unpatentable over Staver

d. Rejection of claims as allegedly being unpatentable over Staver, Lundback and U.S. Patent No. 7,020,531 to Colliou (hereafter "Colliou").

II. Claims 7, 10, 11, 28, 30, 40, 43, 46, 47 and 54-59 Are Patentable Over Samson in view of Staver and Lundback

Independent claims 7, 28 and 43 and respective dependent claims 10, 11, 30, 40, 46, 47 and 54-59 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 6,185,442 to Samson (hereafter "Samson") in view of Staver and Lundback. Applicant respectfully submits that the rejection is moot in view of the claims as amended and the deficiencies of the cited references, whether considered individually or collectively, as discussed below.

A. Deficiencies of Samson

Samson fails to disclose "a flexible tube defining a central axis" and "a suction device … connected to and coaxial with the distal end of the tube" that are configured such that the suction device is removably securable "to myocardial tissue" "by suction applied through the flexible

tube" as recited in claims 1 and 43, and "a flexible tube ... defining a central axis" and "a suction device ... connected to and coaxial with the distal end of the tube..." that are configured such that the suction device is removably securable "to myocardial tissue" "by suction applied through the flexible tube" as recited in claim 28.

Initially, it is alleged that the Samson discloses a "flexible tube" (in which wires 18 are disposed). Office Action (p .2). As shown in Fig. 1, the wires 18 enter the alleged tube 17. However, Samson actually explains that the alleged tube 17 is an "electrode formed of coiled wire 17." Samson (col. 3, lines 48-49). The Office Action has not established, and Samson does not explain, that this coiled wire electrode 17 is a tube. For example, based on the structure shown in Figs. 1 and 3 of Samson, wires 18 may terminate at the proximal end of a solid coiled wire electrode 17.

Nevertheless, Samson further explains that the coiled wire electrode is "provided outside the suction cup [10] for making contact with the vaginal wall. Samson (col. 3, lines 49-50). Accordingly, the coiled wire electrode 17, even assuming that it is a "flexible tube" as recited in the claims, is not used to apply vacuum or suction to secure the suction cup 10 to the head 11 of a fetus. Instead, Samson explains that tube 15 is used for this purpose. Specifically, Samson explains that "the vacuum source is a bellows 14 interconnected to the suction cup [10] by a tube 15." Samson (col. 3, lines 44-46). As shown in Figs. 1 and 3, the tube 15 that is used to apply vacuum or suction is off-axis or not coaxial with the suction cup 10. Rather, the electrode 17 appears to be coaxial with the cup 10. Accordingly, Samson fails to disclose limitations of claims 1, 28 and 43 directed to a flexible tube defining a central axis and a suction device that is connected to and coaxial with a distal end of the tube.

Further, Samson describes a device directed to applying a suction cup 10 to a head 11 of a fetus, in contrast to a suction device that is coaxial with the distal end of the tube and having a flexible distal portion that includes a flexible peripheral sealing surface having a shape and a size for being removably securable to myocardial tissue by suction applied through the flexible tube.

Further, consistent with the concession in page 3 of the Office Action, Samson also fails to disclose "a metallic or metal-based tissue stimulation element ... supported on the peripheral sealing surface of the distal portion of the suction device such that the tissue stimulation element is not located within an inner space defined by the suction device" as recited in claims 1 and 28 and "metallic or metal based tissue stimulation means, carried by the peripheral sealing surface

of the distal portion of the suction device distal surface such that the tissue stimulation means is not located within an inner space defined by the suction device" as recited in claim 43. In contrast, Samson describes "an electrode 16 for making electrical contact with the fetal skin" and that this electrode is mounted "within the suction cup [10]." Samson (col. 3, lines 47-48 (emphasis added). Thus as described by Samson, the electrode 16 is not carried on a peripheral sealing surface of the distal portion, and Samson is further deficient in that the electrode 16 is positioned within the suction cup 10. In this regard, Samson describes a structural configuration that is the opposite of the configuration recited in claims 7, 28 and 43 and, therefore, also teaches away from these claims.

Samson also fails to disclose "a signal line extending from the tissue stimulation element and into the flexible tube for connection to a source of stimulation energy" as recited in claim 7; a metallic or metal-based tissue stimulation element operably "connected to the source of stimulation energy through a signal line extending from the tissue stimulation element and into the flexible tube" as recited in claim 28; and "a signal line extending from the tissue stimulation means and into the flexible tube for connection to a source of stimulation energy" as recited in claim 43. In contrast, Samson describes an electrode 16 that is centrally disposed within a suction cup 10 that does not carry any tissue stimulation elements and, therefore, does not have a signal line extending from a tissue stimulation element carried by a peripheral distal sealing surface and into a flexible tube. Further, such a structural configuration is not necessary in the device described by Samson since the electrode 16 is a centrally disposed within the suction cup 10. Thus, Samson describes a structural configuration that is the opposite of the configurations recited in claims 7, 28 and 43 and teaches away from these claim elements.

Additionally, as conceded in page 3 of the Office Action, Samson fails to disclose the peripheral sealing surface of the suction device is flexible and that a that the electrode 16 is a tissue stimulation element / electrode connected to a source of stimulation energy, which is consistent with the fact that the suction cup 10 device described by Samson is designed for application to a head 11 of a fetus. Office Action (p. 3); Samson (col. 3, lines 44-45).

B. Deficiencies of Staver

Staver is cited for the limited purpose of allegedly disclosing a suction device having an electrode sensor (13) and providing the suction device with an electrode that is place don a

flexible peripheral distal surface of a suction cup or bell 10. Office Action (p. 3). Staver, however, does not cure the substantial deficiencies of Samson and has its own deficiencies.

Initially, Staver fails to disclose "a flexible tube defining a central axis and having a proximal end and a distal end" and "a suction device formed from a flexible material" as recited in claims 7 and 43; "a flexible tube … defining a central axis" and "a suction device formed from a flexible material" as recited in claim 28. Applicant notes that the Office Action no longer relies on the rigid tube 18 described by Staver. Further, the vacuum bell 10 (the alleged "suction device") is "fabricated of a substantially **rigid** electrically-conductive material, such as by **injection molding** an electrically conductive plastic …" Staver (col. 3, lines 53-56 (emphasis added). It is also well understood that such **rigid, injection molded components** are not, and do not form, a suction device formed from a flexible material. In this regard, Staver describes components and material and structural properties thereof that are the opposite of what is recited in claims 7, 28 and 43, particularly considering that it is well understood that "flexible" and "rigid" have contradictory meanings.

Further, Staver fails to disclose "a metallic or metal-based tissue stimulation element configured to emit stimulation energy" as recited in claims 7 and 28 and "metallic or metal based tissue stimulation means, carried by the peripheral sealing surface of the distal portion of the suction device distal surface" as recite din claim 43. It is alleged that component "13" described by Staver is an "electrode sensor." Office Action (p. 3). However, Staver actually explains that this component is an annular member 13 or lower rim of a vacuum bell 10. Staver (col. 4, lines 12-15, with reference to Figs. 1 and 2). This annular member 13 is part of the electrical path from an EKG terminal to the patient's skin, but Staver does not describe the annular member 13 as a stimulation element or electrode as alleged. The description of this member is limited, and with reference to Fig. 7, Staver describes a bell 14 defining a concavity 16, which receives "a mass of electrically conductive material." Staver (col. 5, lines 1-5). As shown in Fig. 7, this material is a "gel" material, which is useful for applying the device to a hairy part of a patient's skin. Staver (col. 5, lines 43-59).

Additionally, Staver fails to disclose a metallic or metal-based tissue stimulation element configured to emit stimulation energy configured "such that the tissue stimulation element is not located within an inner space defined by the suction device" and "wherein the tissue stimulation element is a discrete tissue stimulation element that does not extend around the peripheral

sealing surface" as recited in claims 7 and 28 and "such that the tissue stimulation means is not located within an inner space defined by the suction device" and "wherein the tissue stimulation means does not extend around the peripheral sealing surface" as recited in claim 43. In contrast, Staver describes a configuration that is the opposite of the configuration recited in the claims since Staver specifically describes "a substantially annular-shaped (i.e., toroidal-shaped) mass" positioned within the concavity 16 of the bell 14. Given this particular shape, the mass extends around a surface of the bell 10. Accordingly, Staver describes a structural configuration that is the opposite of the configurations recited in Applicant's claims and teaches away from claims 7, 28 and 43.

Given this particular structural configuration and lack of signal lines (Staver, Figs. 1-7), Staver also fails to disclose "a signal line extending from the tissue stimulation element and into the flexible tube for connection to a source of stimulation energy" as recited in claim 7; a tissue stimulation element "being operably connected to the source of stimulation energy through a signal line extending from the tissue stimulation element and into the flexible tube" as recited in claim 28; and "a signal line extending from the tissue stimulation means and into the flexible tube for connection to a source of stimulation energy" as recited in claim 43.

Staver also fails to disclose such a flexible suction device "having a shape and a size for being removably securable to myocardial tissue" as recited in claims 7, 28 and 43. Notably, the Office Action has not cited any portion of Staver that actually discloses such a configuration. Instead, Staver explains that the first and second apparatus embodiments are used with an EKG machine, and that the bottom portion of the annular member 13 (Fig. 1, first embodiment) and the bottom portion of the bell 14 (Fig. 3, second embodiment) are applied to the skin of a patient, as would be expected when such devices are used with an EKG machine. In fact, Staver explains that a material 20 that is received within an annular concavity 16 of the vacuum bell 14 is a gel material that facilitate application of the apparatus to a particularly hairy area of skin (*e.g.*, a chest area) by affording a substantially adhesive bond with the skin even in hairy areas. Staver (col. 5, lines 43-59). Thus, Staver is not related to a device having stimulation electrodes for application to a myocardial surface.

Staver also fails to disclose a tissue stimulation element or tissue stimulation means that is configured to emit stimulation energy and that is too small to form a transmural lesion in myocardial tissue, the tissue stimulation element being supported on the peripheral sealing

surface of the distal portion of the suction device. Instead, Staver explains that the two devices are used to hold or receive a mass of electrically-conductive material 13/20 that is part of an electrical path from an EKG electrode terminal. As explained in the Appendix submitted with the prior amendment, such devices and electrodes are not used to send electricity into the body.

C. Deficiencies of Lundback

Lundback is cited for the very limited purpose of allegedly disclosing a surgical apparatus comprising a flexible tube (8) and a tissue electrode (tissue contacting side of 30) on the suction device distal surface. Office Action (p. 3, referring to col. 3 and 4, Figs. 1-4 of Lundback). Lundback does not cure the substantial deficiencies of Samson and Staver and has its own deficiencies. Accordingly, the three cited references, even if somehow properly combined, fail to disclose each limitation of each of independent claims 7, 28 and 43 and, therefore, the rejection cannot stand.

Initially, the Office Action refers to a tissue electrode as "the tissue contacting side of 30" but Lundback does not refer to a component identified by "30" and no figure includes "30" as alleged.

Lundback fails to disclose the structural combination of a flexible tube and "a suction device formed from a flexible material, the suction device being connected to and coaxial with the distal end of the tube" as recited in claims 7, 28 and 43. In contrast, the tube 8 identified in the Office Action, and as shown in Fig. 4 of Lundback, has an axis that is orthogonal to an axis defined by other components. Thus, Lundback describes a configuration that is the opposite of the configuration recited in the claims.

Further, Lundback fails to disclose "a suction device formed from a flexible material" as recited in claims 7, 28 and 43. In contrast, Lundback describes a suction device having an electrode plate 1, a sealing component 2, and a back piece 3, and Lundback explains that the back piece 3 is **substantially rigid**. Lundback (Abstract, col. 2, line 27) (emphasis added). Further, the substantially rigid back piece 3 and the sealing ring portion 9 of the sealing component 2 work "as an **integrated, rigid unit** ..." Lundback (col. 4, line 64) (emphasis added). Thus, structure attached to the tube 8 is not "formed from a flexible material" as recited in the claims and the allegation that the collection of components 1-3 is "made from" a flexible material is not correct. Rigid materials are rigid, not flexible.

Lundback also fails to disclose "a metallic or metal-based tissue stimulation element configured to emit stimulation energy and that is too small to form a transmural lesion in myocardial tissue, the tissue stimulation element being supported on the peripheral sealing surface of the distal portion of the suction device" as recited in claims 7 and 28 and "metallic or metal based tissue stimulation means, carried by the peripheral sealing surface of the distal portion of the suction device distal surface" as recited in claim 43. Lundback describes a "sealing component 2" and an electrically conductive frontal surface 4. Lundback (col. 3, line 42; col. 4, line 11). As shown in Figs. 2 and 3 of Lundback, the conductive surface 4 is disposed in a middle portion of the device, not carried by a peripheral surface of sealing element 2.

Further, the device described by Lundback relates to electrocardiography (ECG). As explained in the prior amendment, ECG devices are used to record electrical activity of the heart, but do not send electricity into the body. Applicant also notes that page 4 includes various remarks regarding sensors, but claims 7, 28 and 43 refer to a tissue stimulation element or tissue stimulation means.

Lundback also fails to disclose a metallic or metal-based tissue stimulation element configured to emit stimulation energy and configured "such that the tissue stimulation element is not located within an inner space defined by the suction device" as recited in claims 7 and 28 and "such that the tissue stimulation means is not located within an inner space defined by the suction device" as recited in claim 43. Rather, as shown in Figs. 2 and 3, Lundback describes a stem 5 having a conductive frontal surface 4, which is within the inner space defined by the outer edge of the sealing component 2. Thus, Lundback describes a configuration that is the opposite of the configuration recited in the claims.

Lundback also fails to disclose "a signal line extending from the tissue stimulation element and into the flexible tube for connection to a source of stimulation energy" as recited in claim 7; a tissue stimulation element connected to a source of stimulation energy "through a signal line extending from the tissue stimulation element and into the flexible tube" as recited in claim 28; and "a signal line extending from the tissue stimulation means and into the flexible tube for connection to a source of stimulation energy" as recited in claim 43.

D. Erroneous Quotation of Lundback in Office Action

The Office Action quotes Lundback as disclosing:

> diagnostic devices intended to be attached to the skin by means of the present vacuum-fixed holder are, for example, electrodes for electroencephalography (ECG), electrodes for electromyography (EMG), sensors for skin temperature, humidity, and pH, biosensors and other sensors for indirect or direct measurement of blood gases, intramuscular sensor probes for, e.g., measurement of local peripheral circulation by laser-Doppler techniques, microphones for the registration of heart sounds, optical conductors for observation of skin etc. Therapeutic devices intended to be attached to the skin by means of the present vacuum-fixed holder are, e.g., electrodes for electrical stimulation of muscles, defibrillators, injectors for intramuscular administration of pharmaceuticals, etc.

The Office Action does not cite any section of Lundback that contains this quotation, and Applicant is not able to identify any such section in Lundback. Further, Lundback does not refer to "EMG" or "Doppler" or "therapeutic" devices or other words in the above quotation.

Accordingly, it appears that the Examiner has quoted a section of Lundback that does not exist, and these and other remarks regarding Lundback are not clear. Thus, the remarks on page 9 of the Final Office Action are also misplaced, particularly considering that the cited Lundback reference does not refer to a stimulation electrode and instead describes ECG applications. Lundback (col.2, line 17).

E. Deficiencies of References Collectively

Given these collective deficiencies, the cited references, even if somehow properly combined, fail to disclose each element of each of independent claims 7, 28 and 43. Accordingly, the rejection cannot stand on this basis alone.

Additionally, the allegation that it would be obvious to modify Samson fails to consider that the claims are directed to a device that is attachable to myocardial tissue by suction and emitting stimulation energy to cardiac tissue, whereas Samson is directed to a non-invasive sensing device that is applied to the head of a fetus. Thus, the allegations do not simply involve simple substitution of components, particularly considering the particular structure involving a first, central electrode 16 within the area defined by the suction cup 10 and a second electrode formed of coiled wire 17 outside of the suction cup 10 for making contact with the vaginal wall. Samson (col. 3, lines 47-50).

Further, various references teach away from and disclose a configuration that is the opposite of a configuration recited in the claims. For example, given the particular structure involving a central electrode 16 within the space defined by a suction cup 10, Samson teaches away from a suction device being connected to and coaxial with the distal end of the tube through which suction is applied since the coiled wire 17, rather than a tube 15, is coaxial with the electrode 16 since the electrode 16 is within the center of the suction cup 10. Samson also teaches away from the tissue stimulation element not being located within an inner space defined by the suction device. Given the particular structure described by Staver, this reference teaches away from the tissue stimulation element being a discrete tissue stimulation element that does not extend around the peripheral sealing surface. As another example, given the particular structure described by Lundback, this reference teaches away from a suction device formed from a flexible material (since Lundback describes components that form an integrated, rigid unit) and teaches away from the tissue stimulation element being supported on the peripheral sealing surface of the distal portion of the suction device such that the tissue stimulation element is not located within an inner space defined by the suction device since the conductive surface 4 is within the area defined by the edges of the sealing component 2.

Given these substantial deficiencies, it is respectfully submitted that independent claims 7, 28 and 43 are patentable over the three cited references. Dependent claims 10, 11, 30, 40, 46, 47 and 54-59 incorporate the elements and limitations of respective independent claims 7, 28 and 43 and, therefore, are also believed patentable over these references.

Accordingly, it is respectfully requested that the rejection of these claims under §103(a) be withdrawn.

III. Claims 31-33 and 37-39 Are Patentable Over Samson, Staver, Lundback and Ostroff

Claims 31-33 and 37-39 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Samson in view of Staver and Lundback and further in view of U.S. Patent No. 7,149,575 to Ostroff *et al.* (hereafter "Ostroff"). These claims incorporate the elements of respective independent claims 7 and 28 and, therefore, are also believed patentable over the cited references since Ostroff does not cure the *substantial* and determinative deficiencies discussed above.

Further, Applicant notes that it is stated in the Office Action that the examiner takes "official notice" that it is "trivial" to provide certain modifications. However, Applicant notes that official notice that is unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known. MPEP §2144.03. Otherwise, the other remarks on page 6 are not directed to taking "official notice" but instead are essentially allegations regarding whether certain dimensions are obvious with respect to Staver. *Id.* ("It is never appropriate to rely solely on "common knowledge" in the art without evidentiary support in the record, as the principal evidence upon which a rejection was based).

Nevertheless, the fact remains that the dimensions recited in these claims are on the order of millimeters and fractions thereof, whereas that the device described by Staver includes a member 13 that is operable by squeezing (presumably by a physician or medical assistant) a bulb 1 in order to evacuate the bell 10 and ensure contact of the annular member 13 with the patient's skin. Staver (col. 4, lines 23-42). Thus, the dimensions of such devices are of such a larger magnitude that they can be positioned and manipulated (squeezed) by a user. For example, Staver explains that the bell 10 has a diameter of approximately 2.5 centimeters.

A similar analysis applies to Samson, which describes a bellows 14 that is actuated by hand to attach a suction cup 10 to a head 11 of a fetus. Further, Applicant notes that Fig. 1 shows the central, internal electrode 16 being larger or wider than the coiled wire 17. Thus, it is reasonable to assume, in the absence of a description to the contrary, that the electrode 16 is not on the order or millimeters but instead has dimensions that are larger than dimensions that provide for manual manipulation of the bellows 14.

Accordingly, the general allegation that such dimensions are "trivial" are not consistent with and are not supported by the structural configurations and manual manipulation of devices described by Samson and Staver. Otherwise, pages 6-7 of the Office Action include remarks that attempt to reject claims by attempting to rely on official notice of aspects of a reference that are at odds with what is actually disclosed by those references.

Accordingly, it is respectfully requested that the rejection of these claims under §103(a) be withdrawn.

IV. Claims 34 and 35 Are Patentable Over Samson, Staver, Lundback and Colliou

Claims 34 and 35 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Samson in view of Staver and Lundback and further in view of U.S. Patent No. 7,020,531 to Colliou *et al.* (hereafter "Colliou"). Colliou is cited for the very limited purpose of allegedly disclosing certain stimulation pulses, but Colliou does not cure the substantial and determinative deficiencies discussed above.

Accordingly, it is respectfully requested that the rejection of these claims under §103(a) be withdrawn.

CONCLUSION

Applicant respectfully requests entry of this Amendment and allowance of the application in view of the forgoing remarks. If there are any remaining issues that can be resolved by telephone, Applicant invite the Examiner to kindly contact the undersigned at the number indicated below.

Respectfully submitted,

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